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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,817	10/29/2003	Eyal Raz	UCAL-292	1602

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,817	RAZ ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *10,11,15 and 18-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 12-14, 16-17* is/are rejected.

7)☒ Claim(s) *2, 5-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 10/20/2006. The status of the claims is as follows: claims 1-9, 12-14 and 16-17 are under current examination, and claims 10-11,15 and 18-23 are drawn to non-elected inventions. Election of the following species is acknowledged: idiopathic pulmonary fibrosis, 5'-(TCG)-3' and systemically.

Applicant's election with traverse of Invention I in the reply filed on 10/20/2006 is acknowledged. The traversal is on the ground(s) that examination of the entire application would not be burdensome. This is not found persuasive because examination of eight different pulmonary conditions in combination with six different nucleotide sequences in which four of the sequences contain multiple variables proved to be burdensome after a preliminary search.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 7 is objected to because of the following informalities: in the recitation "where n is any base", it is suggested that "n" is capitalized so that it accurately reads upon the given formula. Appropriate correction is required.

Claims 2 and 5-9 are objected to because of the following informalities: in the recitation "the TLR agonist is a nucleic acid that comprises the sequence 5' CG 3'", it is suggested that "nucleic acid" is changed to nucleic acid sequence or polynucleotide. Appropriate correction is required.

Claims Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 recites the limitation "sequence N-N-N-N " in the given formula $5'N_m$-$(TCG)_n$-N_p-3'. There is insufficient antecedent basis for this limitation in the claim. It is not clear where in the formula this would be found. Appropriate correction or further clarification is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 6-9 and 12-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 15

of U.S. Patent No. 6,498,148 (hereinafter as "Raz"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps are the same. The limitations of the rejected claims of the instant application are: 1. administration of an effective amount of polynucleotide comprising 5' CG 3'to an individual leading to reduction of at least one pathological parameter associated with airway remodeling in an individual suffering from chronic asthma; 2. wherein the polynucleotide further comprises 5'-TGC-3'; 3. the polynucleotide is administered systemically to the individual; and 4. the method further comprises administering an effective amount of an anti-inflammatory agent.

In claims 1-9 and 15, Raz discloses the following limitations: 1. administration of an immunostimulatory sequence (ISS) comprising the sequence 5'-CG-3' for the treatment of asthma; 2. wherein the ISS comprises SEQ ID NO:19; 3. wherein the ISS is administered intramuscularly; and 4. wherein the method further comprises administering an anti-inflammatory agent.

Raz meet the claim limitations above of the instant application. Of note, SEQ ID NO:19 of Raz's patent comprises 5'-TGC-3' (see column 27). Given that the method steps, the population of individuals and the product being administered are the same and thus resulting with the same inherent effect, the claims above are rejected.

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by US 20040241149 (hereinafter as "De Simone"). This application claims benefit to 60/316, 953 filed 09/05/2001. The limitations of the above claims are: 1. a method treating interstitial lung fibrosis, more specifically, idiopathic pulmonary fibrosis; and 2. wherein a polynucleotide comprising the sequence 5'-CG-3' is administered to an individual for treating the disorder.

De Simone discloses a method of administering lactic acid bacteria containing unmethylated cytosine-guanine dinucleotide to treat idiopathic pulmonary fibrosis. See claim 10. Of note, the provisional application 60/316,953 contains all of these limitations. Thus, claims 3-5 are rejected.

Claims 1-2 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kline et al (1998). The limitations of the above claims are: 1. a method of administering to the individual a polynucleotide comprising the sequence 5'-GC-3', wherein at least one pathological parameter associated with airway remodeling is reduced; and 2. wherein the polynucleotide is administered systemically.

Kline et al discloses a method of modulating airway inflammation by CpG oligodeoxynucleotides (ODNs) in a murine model of asthma (see whole document). Further, the oligonucleotides were administered by i.p. injection (see Materials and Methods). Treatment of the mice with CpG ODNs led to marked diminishment of peribronchial eosinophilic inflammation and epithelial activation. As defined in the instant specification, peribronchial eosinophilic inflammation and epithelial activation are both considered pathological parameters. Thus, the above claims are anticipated.

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-4, 14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Simone, and further in view of Britton (2000). The limitations

of the claims are: 1. a method treating interstitial lung fibrosis, more specifically, idiopathic pulmonary fibrosis; and 2. wherein a polynucleotide comprising the sequence 5'-CG-3' is administered to an individual for treating the disorder; 3. wherein the method further comprises administering a corticosteroid, IFN-gamma or a combination of a corticosteroid and IFN-gamma.

As mentioned above, De Simone discloses a method of administering lactic acid bacteria containing unmethylated cytosine-guanine dinucleotide to treat idiopathic pulmonary fibrosis. See claim 10. De Simone does not teach administration of a corticosteroid, IFN-gamma or both in combination with a polynucleotide comprising the sequence 5'-CG-3'.

Britton characterizes the treatment of idiopathic pulmonary fibrosis using a combination of IFN-gamma and prednisolone. It would have been obvious to one of ordinary skill in the art to modify the method steps taught by De Simone and further incorporate administering a combination of IFN-gamma and prednisolone. One would have been motivated to do so because, as disclosed by Britton, the combination of IFN-gamma and prednisolone led to substantial improvements in the condition of patients with idiopathic pulmonary fibrosis (see abstract). There would have been a reasonable expectation of success given that this combination has been well characterized in the prior art to be effective for the treatment of idiopathic pulmonary fibrosis. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see htt://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning
Patent Examiner